UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION	)	MDL No. 2419
THIS DOCUMENT RELATES TO:	)	Dkt. No 1:13-md-2419 (RWZ)
Suits Naming the Tennessee Clinic Defendants	)	

NOTICE OF FILING
SUBPOENA TO THE UNITED STATES FOOD AND DRUG ADMINISTRATION

Defendants Saint Thomas Outpatient Neurosurgical Center, LLC; Howell Allen Clinic, a Professional Corporation; John Culclasure, MD; Debra Schamberg, RN; Vaughan Allen, MD; Specialty Surgery Center, Crossville, PLLC; Kenneth R. Lister, MD; Kenneth Lister, MD, PC; and Donald E. Jones, MD (collectively "Tennessee Clinic Defendants") give notice to the Court and to all parties, pursuant to Federal Rule of Civil Procedure 45(a)(4), of the issuance of a subpoena to the United States Food and Drug Administration ("FDA"). The subpoena commands the production of documents and requires the deposition testimony of an FDA representative pursuant to Federal Rule of Civil Procedure 30(b)(6).[1] The subpoena was emailed to the FDA and to directly involved counsel today, with a copy put in the mail after the service by email. This Notice is filed in the main docket to ensure each party has notice of the subpoena.

[1] The subpoena to the FDA is attached as Exhibit 1 to this Notice.

Respectfully submitted,

GIDEON, COOPER & ESSARY, PLC

/s/ Chris J. Tardio
C.J. Gideon, Jr.*
Chris J. Tardio*
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Attorneys for the Tennessee Clinic Defendants

* Admitted pursuant to MDL Order No. 1.
** Admitted *pro hac vice*.

CERTIFICATE OF SERVICE

I hereby certify that this document filed through the CM/ECF system will be served electronically to the registered participants identified on the Notice of Electronic Filing and copies will be e-mailed or mailed via regular U.S. mail to those participants identified as unregistered this 6th day of March, 2015.

/s/ Chris J. Tardio
Chris J. Tardio

EXHIBIT 1

Subpoena to the FDA

AO 88A (Rev. 02/14) Subpoena to Testify at a Deposition in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Massachusetts

In Re: New England Compounding Pharmacy, Inc. Products Liability Litigation *Plaintiff*

v.

Tennessee Clinic Defendants *Defendant*

Civil Action No. 1:13-md-02419

SUBPOENA TO TESTIFY AT A DEPOSITION IN A CIVIL ACTION

To: United States Food and Drug Administration (FDA)

(Name of person to whom this subpoena is directed)

☑ *Testimony:* **YOU ARE COMMANDED** to appear at the time, date, and place set forth below to testify at a deposition to be taken in this civil action. If you are an organization, you must designate one or more officers, directors, or managing agents, or designate other persons who consent to testify on your behalf about the following matters, or those set forth in an attachment:

Place:	Date and Time:
Gideon, Cooper & Essary, PLC 315 Deaderick Street, Suite 1100 Nashville, TN 37238	05/04/2015 9:00 am CDT

The deposition will be recorded by this method: Stenographical means and by video

☑ *Production:* You, or your representatives, must also bring with you to the deposition the following documents, electronically stored information, or objects, and must permit inspection, copying, testing, or sampling of the material: See attached Duces Tecum, Exhibit 1 to Notice of 30(b)(6) Deposition

The following provisions of Fed. R. Civ. P. 45 are attached – Rule 45(c), relating to the place of compliance; Rule 45(d), relating to your protection as a person subject to a subpoena; and Rule 45(e) and (g), relating to your duty to respond to this subpoena and the potential consequences of not doing so.

Date: 03/05/2015

CLERK OF COURT

OR

Signature of Clerk or Deputy Clerk *Attorney's signature*

The name, address, e-mail address, and telephone number of the attorney representing *(name of party)* Tennessee Clinic Defendants, who issues or requests this subpoena, are:

Chris J. Tardio; 315 Deaderick St., Suite 1100, Nashville, TN 37238; chris@gideoncooper.com; (615) 254-0400

Notice to the person who issues or requests this subpoena

If this subpoena commands the production of documents, electronically stored information, or tangible things before trial, a notice and a copy of the subpoena must be served on each party in this case before it is served on the person to whom it is directed. Fed. R. Civ. P. 45(a)(4).

Civil Action No. 1:13-md-02419

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 45.)

I received this subpoena for *(name of individual and title, if any)* _____

on *(date)* _____ .

❒ I served the subpoena by delivering a copy to the named individual as follows: _____

_____

_____ on *(date)* _____ ; or

❒ I returned the subpoena unexecuted because: _____

_____ .

Unless the subpoena was issued on behalf of the United States, or one of its officers or agents, I have also tendered to the witness the fees for one day's attendance, and the mileage allowed by law, in the amount of $ _____ .

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc.:

Federal Rule of Civil Procedure 45 (c), (d), (e), and (g) (Effective 12/1/13)

(c) Place of Compliance.

(1) ***For a Trial, Hearing, or Deposition.*** A subpoena may command a person to attend a trial, hearing, or deposition only as follows:

(A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or

(B) within the state where the person resides, is employed, or regularly transacts business in person, if the person

(i) is a party or a party's officer; or

(ii) is commanded to attend a trial and would not incur substantial expense.

(2) ***For Other Discovery.*** A subpoena may command:

(A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and

(B) inspection of premises at the premises to be inspected.

(d) Protecting a Person Subject to a Subpoena; Enforcement.

(1) ***Avoiding Undue Burden or Expense; Sanctions.*** A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.

(2) ***Command to Produce Materials or Permit Inspection.***

(A) *Appearance Not Required.* A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.

(B) *Objections.* A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing, or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:

(i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

(ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

(3) ***Quashing or Modifying a Subpoena.***

(A) *When Required.* On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:

(i) fails to allow a reasonable time to comply;

(ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);

(iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or

(iv) subjects a person to undue burden.

(B) *When Permitted.* To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:

(i) disclosing a trade secret or other confidential research, development, or commercial information; or

(ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.

(C) *Specifying Conditions as an Alternative.* In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:

(i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and

(ii) ensures that the subpoenaed person will be reasonably compensated.

(e) Duties in Responding to a Subpoena.

(1) ***Producing Documents or Electronically Stored Information.*** These procedures apply to producing documents or electronically stored information:

(A) *Documents.* A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.

(B) *Form for Producing Electronically Stored Information Not Specified.* If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.

(C) *Electronically Stored Information Produced in Only One Form.* The person responding need not produce the same electronically stored information in more than one form.

(D) *Inaccessible Electronically Stored Information.* The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

(2) ***Claiming Privilege or Protection.***

(A) *Information Withheld.* A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:

(i) expressly make the claim; and

(ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.

(B) *Information Produced.* If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.

(g) Contempt.

The court for the district where compliance is required—and also, after a motion is transferred, the issuing court—may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

For access to subpoena materials, see Fed. R. Civ. P. 45(a) Committee Note (2013).

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION	)	**MDL No. 2419**
	)	**Dkt. No 1:13-md-2419 (RWZ)**
THIS DOCUMENT RELATES TO:	)	
All cases	)	

Notice of 30(b)(6) Deposition

Defendants Saint Thomas Outpatient Neurosurgical Center, LLC; Howell Allen Clinic, a Professional Corporation; John Culclasure, MD; Debra Schamberg, RN; Vaughan Allen, MD; Specialty Surgery Center, Crossville, PLLC; Kenneth R. Lister, MD; Kenneth Lister, MD, PC; and Donald E. Jones, MD (collectively "Tennessee Clinic Defendants"), pursuant to Federal Rule of Civil Procedure 30(b)(6), come now and give notice that the oral and videotaped deposition of the United States Food and Drug Administration ("FDA"), as an organization, will be taken on the topics detailed below. The FDA shall identify the person(s) who will speak on its behalf on each topic at least seven (7) days before the deposition(s).

The deposition will be taken on May 4, 2015, beginning at 9:00 a.m. (CDT) and continuing until completed. The deposition will take place at the offices of Gideon, Cooper & Essary, PLC, 315 Deaderick St., #1100, Nashville, TN 37238. The deposition will be recorded by stenographical means and by video.

Pursuant to Federal Rule of Civil Procedure 30(b)(6), the FDA's designee(s) shall be prepared to testify regarding the following subjects:

FDA's authority to investigate, inspect, regulate, and take action against NECC

1. The FDA's authority to investigate, inspect, regulate, and take enforcement action against NECC from 2002 through the meningitis outbreak, particularly in light of the information FDA learned about NECC's operations beginning in 2002.

2. The FDA's application of Compliance Policy Guide § 460.200 (2002) when making the decision whether to regulate compounding pharmacies like NECC (*i.e.*, compounding pharmacies with large-scale operations similar to conventional drug manufacturers), both before the meningitis outbreak and since the meningitis outbreak.

3. The FDA's internal policies (written or otherwise), procedures (written or otherwise), and training of staff from 2002 to the time of the meningitis outbreak on the (1) inspection of compounding pharmacies, (2) when regulatory action was appropriate against compounding pharmacies, and (3) distinguishing between traditional compounding, large-scale compounding similar to drug manufacturing (now called "outsourcing facilities"), and conventional drug manufacturers.

4. Generally, FDA's authority to take enforcement actions against drug manufacturers, and how that authority can be exercised (*i.e.*, generally, the differences between the types of enforcement actions available to the FDA, *e.g.*, private censures, warning letters, seizures, injunctions, criminal actions, civil penalties, *etc.*).

5. The decision by FDA to, following the meningitis outbreak, inspect and take action against 30+ compounding pharmacies.

FDA's investigation, inspections, regulation, and actions related to NECC

6. All complaints about NECC known by the FDA prior to the meningitis outbreak and the FDA's response to these complaints, including the internal decision-making regarding whether and how to investigate, inspect, and take action against NECC. The complaints and related investigations, inspections, and actions that the witness should be prepared to testify regarding include, but are not limited to:

a. Investigation in March 2002 and subsequent inspection on April 16, 2002 (and related 483)

b. Investigation in October 2002 and subsequent inspection (483 issued February 10, 2003)

c. 2002-03 internal meetings at FDA related to FDA's role in regulating NECC, as described in the February 24, 2003, FDA internal memorandum

d. The inspection request to the Investigations Branch of the New England District Office of the FDA dated June 2, 2004

e. The investigation and inspection conducted in September 2004 related to NECC production of trypan blue

f. Complaints about NECC in January and February 2006[1]

g. The 2006 Warning Letter issued to NECC (including the findings underlying the letter)

h. June 2007 MedWatch reports to FDA about NECC related to re-packaging of Avastin

i. June 2008 complaints to the FDA related to NECC betamethasone

j. September 16, 2008, FDA assignment for inspection of NECC, and the failure to do the inspection[2]

[1] One complaint emanated from Texas. One appears to have originated from within the FDA.
[2] This includes actions in February 2009 and September 2009 documented in internal emails and memoranda indicating FDA's plan to (re-)inspect NECC and take immediate action (which, apparently, did not occur).

k. October 31, 2008, letter to NECC asserting that FDA has the authority to take action and that FDA will re-inspect NECC

l. Reports from anonymous informants in October 2009 and July 2010 about Ameridose and its leadership (leadership shared with NECC) forging sterility documents and knowingly not following proper sterility procedures

m. 2011 reports from the Colorado Board of Pharmacy and the FDA's failure to act against NECC based on these reports.

7. Any and all complaints about NECC made to the FDA or actions by the FDA in response to complaints about NECC not specifically referenced in Number 6(a)-(m).

8. Any and all correspondence and communications between the FDA and NECC (including its owners, agents, employees, and representatives) not specifically referenced in Number 6(a)-(m).

9. Any and all correspondence and communications between the FDA and state pharmacy boards related to NECC not referenced in Number 6(a)-(m).

10. Whether, (1) based on information learned by the FDA about NECC prior to the meningitis outbreak and (2) considering the statutory factors set out in 503A and the factors set out in the 2002 CPG, NECC was operating like a conventional drug manufacturer (or, at a minimum, operating on a scale not akin to a traditional compounder), subjecting it to FDA regulatory authority.

11. The FDA's authority prior to the meningitis outbreak to share the information FDA had about NECC with the State of Massachusetts and recommend to the State that it take enforcement action against NECC's state license.

State of Massachusetts

12. The FDA's cooperation with the State of Massachusetts in investigating, inspecting, and taking action against NECC prior to the meningitis outbreak.

13. Whether the FDA believes it was the State of Massachusetts' responsibility to take enforcement action against NECC given the information known by the FDA and the State of Massachusetts about NECC prior to the meningitis outbreak.

The information known by the FDA about NECC and whether/how it was made public

14. What, if any, of the information known by the FDA about NECC's failure to follow federal law, state law, or industry standards for production of drugs was made publicly available prior to the meningitis outbreak and the steps necessary for potential customers of NECC to obtain the information from the FDA.

15. What information known by the FDA about NECC's failure to follow federal law, state law, or industry standards for production of drugs was available to potential customers of NECC had they requested such information from the FDA prior to the meningitis outbreak.

16. Whether the FDA issued any alerts to health care providers prior to the meningitis outbreaks related to NECC (*e.g.*, that it was unsafe to purchase from NECC; that it was unsafe to purchase certain drugs from NECC; that NECC was operating in violation of federal or state law; *etc.*).

FDA's investigation and inspection of, and action against NECC, following the meningitis outbreak

17. The findings of the FDA based on its investigation and inspection of NECC following the meningitis outbreak.

18. The source of the information contained in the NECC customer lists published by the FDA following the outbreak.

Documents

19. The documents that the witness(es) is requested to produce in the *duces tecum* attached as exhibit 1 to this Notice.

Respectfully submitted,

GIDEON, COOPER & ESSARY, PLC

/s/ Chris J. Tardio
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Attorneys for the Tennessee Clinic Defendants

* Admitted pursuant to MDL Order No. 1.
** Admitted *pro hac vice*.

CERTIFICATE OF SERVICE

I certify that this document filed through the CM/ECF system will be served electronically to the registered participants identified on the Notice of Electronic Filing and copies will be e-mailed or mailed via regular U.S. mail to those participants identified as unregistered this 6th day of March, 2015.

/s/ Chris J. Tardio
Chris J. Tardio

EXHIBIT 1

Duces Tecum to Notice

EXHIBIT 1 – *DUCES TECUM*

1. The witness's most current professional resume or *curriculum vitae.*

2. Any and all documents, including internal memoranda, internal communications, and external communications, related to FDA's investigation, inspection, and regulation of, and enforcement action against, NECC prior to the meningitis outbreak.

   Further instructions:

   > *To the extent these documents have already been produced to the Tennessee Clinic Defendants in response to the previous FOIA request, please simply confirm this.*
   >
   > *To the extent these documents have been posted on a website for public access (*e.g., *the FDA FOIA "reading room"), please identify the specific website where the Tennessee Clinic Defendants can access the entirety of the documents.*
   >
   > *If some documents are withheld on assertion of privilege or for any other reason, please identify the documents with reasonable particularity and the reason the documents have been withheld.*

3. All treatises, scholarly journals, professional studies, professional literature, or similar documents the witness intends to rely upon in giving testimony responsive to this Notice.

4. Any and all documents, not privileged, reviewed or relied on by the witness in preparation for giving testimony pursuant to the Notice.

5. FDA's internal policies, procedures, or training materials in place from 2002 to the time of the meningitis outbreak related to (1) the investigation, inspection, and regulation of, and enforcement action against, large-scale compounding pharmacies (compounding pharmacies operating beyond the definition of traditional compounding and acting more similar to conventional drug manufacturers) or (2) how FDA defined a traditional compounding pharmacy versus a large-scale compounding pharmacy acting more similar to a conventional drug manufacturer.

6. Any and all of NECC's documents, photographs, film, video, or exhibits obtained by the FDA in response to the meningitis outbreak.